

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number

September 1, 2004

Filing Date

First Named Inventor

Miller, Richard L.

Confirmation Number

2906

Attorney Case Number

58751US010

U.S. Patent Documents

Exam. Init.*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Doc. Number-(Kind Code if Known)			
	A1	US- 4,689,338	08-25-1987	Gerster	
	A2	US- 4,929,624	05-29-1990	Gerster et al.	
	A3	US- 4,988,815	01-29-1991	André et al.	
	A4	US- 5,037,986	08-06-1991	Gerster	
	A5	US- 5,175,296	12-29-1992	Gerster	
	A6	US- 5,238,944	08-24-1993	Wick et al.	
	A7	US- 5,266,575	11-30-1993	Gerster et al.	
	A8	US- 5,268,376	12-07-1993	Gester	
	A9	US- 5,346,905	09-13-1994	Gerster	
	A10	US- 5,352,784	10-04-1994	Nikolaides et al.	
	A11	US- 5,367,076	11-22-1994	Gerster	
	A12	US- 5,389,640	02-14-1995	Gerster et al.	
	A13	US- 5,395,937	03-07-1995	Nikolaides et al.	
	A14	US- 5,446,153	08-29-1995	Lindstrom et al.	
	A15	US- 5,482,936	01-09-1996	Lindstrom	
	A16	US- 5,693,811	12-02-1997	Lindstrom	
	A17	US- 5,741,908	04-21-1998	Gerster et al.	
	A18	US- 5,756,747	05-26-1998	Gerster	
	A19	US- 5,939,090	08-17-1999	Beaurline et al.	
	A20	US- 6,028,076	02-22-2000	Hirota et al.	
	A21	US- 6,039,969	03-21-2000	Tomai et al.	
	A22	US- 6,069,149	05-30-2000	Nanba et al.	
	A23	US- 6,083,505	07-04-2000	Miller et al.	
	A24	US- 6,110,929	08-29-2000	Gerster et al.	
	A25	US- 6,194,388	02-27-2001	Krieg et al.	
	A26	US- 6,194,425	02-27-2001	Gerster et al.	
	A27	US- 6,207,646	03-27-2001	Krieg et al.	
	A28	US- 6,239,116	05-29-2001	Krieg et al.	

*Examiner:	/Geeta Kadambi/	Date Considered:	09/05/2008
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		Doc. Number-(Kind Code if Known)			
	A29	US- 6,245,776	06-12-2001	Skwierczynski et al.	
	A30	US- 6,329,381	12-11-2001	Kurimoto et al.	
	A31	US- 6,331,539	12-18-2001	Crooks et al.	
	A32	US- 6,339,068	01-15-2002	Krieg et al.	
	A33	US- 6,376,501	04-23-2002	Isobe et al.	
	A34	US- 6,376,669	04-23-2002	Rice et al.	
	A35	US- 6,387,938	05-14-2002	Mizuguchi et al.	
	A36	US- 6,406,705	06-18-2002	Davis et al.	
	A37	US- 6,426,334	07-30-2002	Agrawal et al.	
	A38	US- 6,451,810	09-17-2002	Coleman et al.	
	A39	US- 6,476,000	11-05-2002	Agrawal	
	A40	US- 6,518,265	02-11-2003	Kato et al.	
	A41	US- 6,525,064	02-25-2003	Dellaria et al.	
	A42	US- 6,541,485	04-01-2003	Crooks et al.	
	A43	US- 6,545,016	04-08-2003	Dellaria et al.	
	A44	US- 6,545,017	04-08-2003	Dellaria et al.	
	A45	US- 6,558,951	05-06-2003	Tomai et al.	
	A46	US- 6,573,273	06-03-2003	Crooks et al.	
	A47	US- 6,656,938	12-02-2003	Crooks et al.	
	A48	US- 6,660,735	12-09-2003	Crooks et al.	
	A49	US- 6,660,747	12-09-2003	Crooks et al.	
	A50	US- 6,664,260	12-16-2003	Charles et al.	
	A51	US- 6,664,264	12-16-2003	Dellaria et al.	
	A52	US- 6,664,265	12-16-2003	Crooks et al.	
	A53	US- 6,667,312	12-23-2003	Bonk et al.	
	A54	US- 6,670,372	12-30-2003	Charles et al.	
	A55	US- 6,677,347	01-13-2004	Crooks et al.	
	A56	US- 6,677,348	01-13-2004	Heppner et al.	

*Examiner: /Geeta Kadambi/ Date Considered: 09/05/2008

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		Doc. Number-(Kind Code if Known)			
	A57	US- 6,677,349	01-13-2004	Griesgraber	
	A58	US- 6,683,088	01-27-2004	Crooks et al.	
	A59	US- 6,756,382	06-29-2004	Coleman et al.	
	A60	US- 6,854,444	02-15-2005	Plagge et al.	
	A61	US- 2002/0016332	02-07-2002	Slade	
	A62	US- 2002/0055517	05-09-2002	Smith	
	A63	US- 2002/0110840	08-15-2002	Tomai et al.	
	A64	US- 2003/0133913	07-17-2003	Tomai et al.	
	A65	US- 2003/0199538	10-23-2003	Skwierczynski et al.	
	A66	US- 2004/0014779	01-22-2004	Gorden et al.	

Foreign Patent Documents

Exam. Init.*	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation (Check if yes)
		Ctry. Code	Number-KindCode (If known)				
	B1	PCT	WO 02/22125	03-21-2002			
	B2	PCT	WO 02/24225	03-28-2002			
	B3	PCT	WO 03/045391	06-05-2003			
	B4	PCT	WO 04/058759	07-15-2004			
	B5	PCT	WO 05/020995	03-10-2005			
	B6	CA	2 346 634	06-08-2000			
	B7	JP	9-255926	03-26-1999			
	B8	EP	0 394 026	09-29-1993			
	B9	EP	1 256 582	11-13-2002			

OTHER DOCUMENTS

Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Translation (Check if yes)
	C1	Davis et al., "Self-Administered Topical Imiquimod Treatment of Vulvar Intraepithelial Neoplasia", Journal of Reproductive Medicine, Volume 45, Number 8, p 619-623, Aug. 23	
	C2	Diaz-Arrastia et al., "Clinical and Molecular Responses in High-Grade Intraepithelial Neoplasia Treated with Topical Imiquimod 5%", Clinical Cancer Research, Volume 7, p 3031-3033, October 2001	

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	C3	Fujisawa et al., "Effect of a Novel Topical Immunomodulator, S-28463, on Keratinocyte Cytokine Gene Expression and Production," abstract, Journal of Interferon and Cytokine Research, 16/7, p. 555-559, (1996).	
	C4	Geisse et al., "Imiquimod 5% cream for the treatment of superficial basal cell carcinoma: A double-blind, randomized, vehicle-controlled study", J. Am. Acad. Dermatol., 47(3): 390-398	
	C5	Hennge et al., "Topical immunomodulators—progress towards treating inflammation, infection, and cancer.", abstract, Lancet Infectious Disease, 1(3), p.189-198, (2001).	
	C6	Jayne et al., "Treatment of Vulvar Intraepithelial Neoplasia 2/3 with Imiquimod", The Journal of Reproductive Medicine, Volume 47, Number 5, p 395-398, May 2002	
	C7	Kaspari et al., "Application of imiquimod by suppositories (anal tampons) efficiently prevents recurrences after ablation of anal canal condyloma", British Journal of Dermatology, 147, p 757-759, (2002)	
	C8	Pehoushek et al., "Imiquimod and 5% Fluorouracil Therapy for Anal and Perianal Squamous Cell Carcinoma In Situ in an HIV-1-Positive Man", Arch Dermatol. Volume 137, p 14-16, January 2001	
	C9	Salat et al., "Imiquimod 5% anal tampons for intraanal condylomata acuminata", International Journal of STD & AIDS, Volume 13, Supplement 1, p 54, (2002)	
	C10	Shumack et al., "Efficacy of Topical 5% Imiquimod Cream for the Treatment of Nodular Basal Cell Carcinoma", Arch. Dermatol., 138: 1165-1178 (2002)	
	C11	Todd et al., "The effects of 5% imiquimod Cream on High-Grade Vulval Intraepithelial Neoplasia", Gynecologic Oncology, 85, p 67-70, (2002)	
	C12	Travis et al., "Successful Treatment of Vulvar Intraepithelial Neoplasia with Topical Imiquimod 5% Cream in a Lung Transplanted Patient", Letters to the Editor, Acta Derm Venereol 82, p 475-476	
	C13	Van Seters et al., "Imiquimod in the Treatment of Multifocal Vulvar Intraepithelial Neoplasia 2/3, Results of a Pilot Study", The Journal of Reproductive Medicine, Volume 47, Number 9, p. 701-705, September 2002	

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